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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/613,753

07/03/2003

Brenda Reeve

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7590

06/15/2006

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EXAMINER

SOROUGH, LAYLA

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/613,753	Applicant(s) REEVE, BRENDA	
	Examiner Layla Soroush	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/17/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

The Office Action is in response to the Preliminary Amendment filed July 3, 2003.

Claims 1-23 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 10-19, 21-22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gervais (Pat. No. 6,340,695 - IDS).

Gervais teaches a rapid onset formulation comprising pyridoxine HCl and doxylamine succinate useful in the treatment of nausea and vomiting comprising administration of a therapeutically effective amount of the composition (see, column 1 lines 5-11, column 11 lines 1-3, and specifically claim 27). The reference does not specifically teach "reducing post-surgical vomiting" or "treating post-surgical vomiting" comprising the administration before, during after (at regular intervals), before anesthesia, on an outpatient bases, on an evening prior to, a morning of the day of,

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immediately after surgery, as recited in claims 1-6, 13, 15-16, 18, and 19. However, the reference teaches the formulation of Doxylamine succinate and pyridoxine hydrochloride are used in the human and veterinary fields of medicine whenever symptoms of nausea and/or vomiting require medical intervention (column 2, lines 56-59).” The reference teaches oral dosage forms (column 2, lines 61-63), as recited in claim 7. Additionally, the reference teaches in Example 1 a formulation wherein pyridoxine HCl and doxylamine succinate each weigh 10 mg/ tab, as recited in claims 11 and 23. The formulation and its components are in pharmaceutically acceptable carriers (e.g., magnesium trisilicate) (column 4, see Table 1), meeting the limitations of claims 10 and 22. The treatment of nausea and vomiting is especially, but not limited to, during pregnancy (column 1 lines 5-11), meeting the limitation of claim 14. The limitation “at substantially the same time,” recited in claims 17 and 21, are met because the reference teaches the formulation in a tablet, pill or encapsulated beads or solution. Hence, the components are administered at “substantially the same time” in any form recited above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the Doxylamine succinate and pyridoxine HCl formulation to reduce post-surgical vomiting because the reference teaches the treatment of vomiting and nausea in general. The motivation to administer the said formulation is because the prior art teaches the ingredients in treating nausea and vomiting (see claim 25, column 10, lines 62-64, and column 2, lines 56-61). Therefore, a skilled artisan would have reasonable expectation of treating post operative nausea and vomiting because

Gervais teaches that the said formulation can be administered whenever symptoms of vomiting and nausea require medical intervention.

In reference to Claim 12, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the dose range of Gervais compound by routine experimentation (see 2144.05 11). The motivation to optimize the dose range of the Gervais' final formulation is because he would have had a reasonable expectation of success in achieving the safest clinical outcome.

Claims 8, 9, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gervais (Pat. No. 6,340,695) as applied to claims 1-7, 10-19, 21-22, and 23 above, and further in view of. Ansel et al.

Gervais is as discussed above.

The preferred formulation of the Gervais invention is in the form of an oral dosage form such as a tablet, pill or encapsulated beads or solution (column 2, lines 61-64). Further, the art teaches in the "most preferred embodiment, the formulation contains a core coated with an aqueous enteric coating. The core comprises the active ingredients pyridoxine HCl and doxylamine succinate (column 3, lines 39-42).

Gervais does not specifically teach a delayed release formulation.

Ansel et al. teaches delayed release products usually are enteric-coated tablets or capsules designed to pass through the stomach unaltered, later to release their medication within the intestinal tract (page 229, column 1, first paragraph).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the identical enteric-coated tablet with the composition. The motivation to make such an incorporation is because Gervais teaches the preferred embodiment of the invention is a formulation that is enterically coated and further by Ansel's teaching that delayed release products are usually enterically-coated. The skilled artisan would have reasonable expectation of producing a similar composition with similar efficacy and delayed release properties.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 13-18 and 19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-29, and 30 of U.S. Patent Application No. 09/885,051. Although the conflicting claims are not

identical, they are not patentably distinct from each other because the claims of the co-pending application recites a method of treating nausea and vomiting comprising administering a therapeutically effective amount of an enterically-coated pyridoxine HCl and doxylamine succinate rapid onset formulation, whereas the instant claims are to method of reducing post-surgical vomiting comprising administering to a patient a therapeutically effective amount of pyridoxine HCl and doxylamine succinate. To one of ordinary skill in the art it would be obvious to administer the identical composition with the expectation of producing similar efficacy and results.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER